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Sanitary/Phytosanitary/Food Safety Maximum Levels for Fusarium in Food Published 2005

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Report Highlights:

The Commission has established harmonized maximum levels for fusarium toxins in food. Maximum levels in corn will come intro force on July 1, 2007. All other levels will become applicable on July 1, 2006.

Includes PSD Changes: No Includes Trade Matrix: No Unscheduled Report Brussels USEU [BE2] Commission Regulation 856/2005 establishes maximum levels for fusarium toxins including deoxynivalenol (DON), zearalenone (ZEA) and fumonisins on cereals and cereal-based foods. (The full text of the regulation can be downloaded from

http://europa.eu.int/eurlex/lex/LexUriServ/site/en/oj/2005/I_143/I_14320050607en00030008.pdf). The accompanying sampling plan was published in Commission Directive 2005/38/EC (http://europa.eu.int/eur-

lex/lex/LexUriServ/site/en/oj/2005/I_143/I_14320050607en00180026.pdf)

The levels are as follows:

deoxynivalenol (DON)

Product	Maximum Level (ppb)
1. Unprocessed cereals other than durum wheat, oats and corn	1,250
2. Unprocessed durum wheat and oats	1,750
3. Unprocessed corn	a/
4. Cereal flour, including corn flour, grits and meal	750
5. Bread, pastries, biscuits, cereal snacks and breakfast cereals	500
6. Pasta (dry)	750
7. Processed cereal-based food for infants and baby food	200

a/ If no specific level is fixed before July 1, 2007 the level of 1,750 ppb will apply as of that date

zearalenone (ZEA)

Product	Maximum
	Level (ppb)
1. Unprocessed cereals other than corn	100
2. Unprocessed corn	a/
3. Cereal flour except corn flour	75
4. Corn flour, meal, grits and refined corn oil	b/
5. Bread, pastries, biscuits	50
Corn snacks and cornflakes	c/
Other cereal snacks and breakfast cereals	50
6. Processed corn-based foods for infants and young children	d/
Other processed cereals based foods for infants and baby-food	20

a/ If no specific level is fixed before July 1, 2007 the level of 200 ppb will apply as of that date

b/ If no specific level is fixed before July 1, 2007 the level of 200 ppb will apply as of that date

c/ If no specific level is fixed before July 1, 2007 the level of 50 ppb will apply as of that date d/ If no specific level is fixed before July 1, 2007 the level of 20 ppb will apply as of that date

Fumonisins (sum of FB1 and FB2)

Product	Maximum
	Level (ppb)
1. Unprocessed corn	a/
2. Corn grits, meal and flour	b/

3. Corn based foods for direct consumptions with the exception of 2 and 4	c/
4. Processed corn based foods for infants and baby food	d/

a/ If no specific level is fixed before July 1, 2007 the level of 2,000 ppb will apply as of that date

b/ If no specific level is fixed before July 1, 2007 the level of 1,000 ppb will apply as of that date

c/ If no specific level is fixed before July 1, 2007 the level of 400 ppb will apply as of that date

d/ If no specific level is fixed before July 1, 2007 the level of 200 ppb will apply as of that date

When Will the New Levels Apply?

The new maximum levels will enter into force on July 1, 2006 for all cereals except corn. Maximum levels for corns will only become applicable as of July 1, 2007.

Impact on Third Countries

At this point in time the impact on imports from third countries including the U.S. is rather unclear. The EU grain traders association had expressed concerns when this measure was still at a draft stage based on input from the Canadian grain industry. Those concerns primarily related to the levels of DON.

The US Government commented on the measures when it was notified to the WTO (comments sent on Feb 23, 2005). The published levels are unchanged from the levels transmitted in notification G/SPS/N/EEC/253. In these comments, the US Government pointed out that in the U.S. no regulatory levels have been established on fusarium toxins. The United States has established for the industry an advisory level of 1.0 mg/kg for DON in finished wheat products (e.g., flour, bran, germ) and guidance levels for fumonisins in various corn products (available at http://www.cfsan.fda.gov/~dms/fumongu2.html). The advisory and guidance levels are recommended maximum levels in human foods and in animal feeds that the United States considers achievable with the use of good agricultural and good manufacturing practices.

The U.S. Government furthermore referred to the work done by the Codex Committee on Food Additives and Contaminants (CCFAC) on this issue, commenting that Codex has considered that not sufficient data were available to establish maximum levels. Also, the scientific basis for setting maximum limits was questioned.

Note: The 37th CCFAC that took place in April 2005 agreed to establish a drafting group, led by the United States, to develop a discussion paper on DON containing comprehensive relevant data on the occurrence and effect of processing to JECFA for consideration at its next session.

Relation with the German Legislation on Mycotoxins

Since February 2004, Germany has its own national maximum tolerance levels for DON and ZEA in place. These levels were fixed for food. This is why they seem to be stricter than the EU levels, which are set for raw grains.

The levels are as follows:

deoxynivalenol (DON)

Product	Maximum	
	Level (ppb))

grains for direct consumption and grain products	500
bread and fine bakery products	350

zearalenone (ZEA)

Product	Maximum
	Level (ppb)
grains for direct consumption and grain products	50

The general rule is that EU rules supercede national regulations. This implies that as soon as the new EU maximum levels for DON and ZEA become effective they will also apply to Germany.

However, there is still the theoretical option that for health protection reasons national government wish to apply stricter tolerance levels. This approach requires scientific proof that EU level are not sufficient to reflect national health interests. In this case it seems quite unlikely that Germany would deviate from EU levels. In meetings with government officials during recent months it was mentioned that EU fusarium levels will replace national levels.

Other Upcoming Legislation

The Commission is also in the process of establishing maximum levels for deoxynivalenol (DON), zearalenone (ZEA) and ochratoxin A in feed.

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Related reports from USEU Brussels:

Report Number	Title	Date Released
E35073	Guidance Document for Aflatoxin Controls	04/22/05

These reports can be accessed through our website www.useu.be/agri or through the FAS website http://www.fas.usda.gov/scriptsw/attacherep/default.asp.